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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,833	10/20/2005	Yves Frere	0512-1299	6305

466 7590 07/21/2009
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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
07/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,833	FRERE ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-11,13-15 and 17-234* is/are pending in the application.

4a) Of the above claim(s) *2-5,7-11,13-15 and 19-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refer to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference)

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 8, 2009 has been entered.

Election/Restrictions

To summarize the current election, applicant elected invention group III.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what applicant means by the terms "hydrophilic" and "lipophilic" in the context of the invention. In example 1 of the instant specification, a set of capsules are made composed of insulin, poly(vinyl alcohol), and poly(L-lactate) or poly(D,L-lactate-co-glycolate), where poly(vinyl alcohol) is ultimately present on the outer surface of the capsules. It is not clear which of these components are considered by applicant to be lipophilic. In another instance, applicant points to an article in Advanced Drug Delivery Reviews to demonstrate the chemical species claimed to give the vector an "essentially lipophilic nature" (see paragraph 37). However the only surface modifications taught by this reference involve the application of chitosan, poly(vinyl alcohol), of cholesterol modified poly(acrylic acid) to the surface of liposomes. So it is not clear what compounds are intended as lipophilic and how to identify them when those exemplified appear to also be classified as hydrophilic (e.g. chitosan, poly(vinyl alcohol), and poly(acrylic acid)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar (Journal of Pharmacy and Pharmaceutical Sciences 2000 3: 234-258) in view of Keller (previously cited) and Baker et al. (previously cited).

Kumar teaches particles for oral delivery (see page 234 column 2 paragraph 1).In one embodiment, lipid coated chitosan particles are taught. Specifically, chitosan and 5-fluorouricil are taught present in the core of a particle that is then coated with the lipid dipalmitoyl phosphalidyl choline (DPPC) (see page 247 column 2 lines 1-14). The dried, lipid coated particles are taught to have a diameters 250 nm to 300 nm (page 247 column 2 17-19; instant claim 1). Although not explicitly taught by Kumar, it is the position of the Examiner that the interaction between the chitosan core and the DPPC

coating would meet the claim limitation of "weak bonds". As figure 9 of Kumar demonstrates, chitosan is a positively charged molecule. The phosphate groups of the DPPC are negatively charged, thus electrostatic interaction would likely occur between these molecules and those of the chitosan. Further, hydrogen bonds are also possible between the carbonyl groups of the DPPC and the amines in the chitosan structure, which would also qualify as "weak bonds". Kumar et al. also does not explicitly teach the inclusion of these particles in a gastric protection with a lipophilic compound.

Keller teaches a drug containing particulate lipophilic vector that is included with a liquid carrier (propylene glycol) in a gelatin capsule, where the capsule is coated with an enteric polymeric coating (see column 4 lines 22-29 and example 1; instant claims 1 and 18). Such coatings are well known to withstand the acidic environment of the stomach, thereby protecting its cargo and facilitating its delivery in the intestine. Further Keller teaches that the gelatin capsules are negatively affected by the presence of water in the material they contain (see column 4 lines 5-6). Keller does not teach that this liquid carrier is lipophilic.

Baker et al. teach a drug containing lipophilic particulate composition that is taught to be delivered with a pharmaceutically acceptable carrier (see column 25 lines 14-27 and column 26 lines 3-4). Baker et al. go on to teach a set of glycols and oils that are particularly envisioned as such a carrier, where a variety of animal oils, mineral oils, and organic oils are named (see column 26 lines 6-10; instant claims 1 and 17).

The teachings of Keller et al. provide an enteric coated gelatin capsule that holds a liquid carrier (polyethylene glycol) and active containing particulates. Baker teaches

equivalent liquid carriers for pharmaceutical particulates that include both glycols and oils. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine these teachings and use one of the oils taught by Baker et al. instead of the glycol used as the liquid carrier in the gelatin capsule of Keller et al. It also would have been obvious to employ this gelatin capsule configuration of Baker et al. and Keller et al. in the invention as an oral carrier for the particles of Kumar since they are known for oral delivery. Further, gelatin capsules were well known in the art as oral carriers at the time of the invention and therefore were an option well within the technical grasp of one of ordinary skill in the art at the time of the invention. Based upon applicant's disclosure of the same components and configuration as a part of the invention (see instant specification paragraphs 35, 38-40, 43, 49, 53, and 57), it is the position of the Examiner that the composition of Kumar in view of Keller and Baker et al. would also have the same properties (allows said pharmacologically active substance to pass from the intestinal lumen to the blood, optionally via the interstitial fluid, without denaturation or degradation of said at least one pharmacologically active substance, and upon contact with microvilli present in the intestine during passage through the intestinal lumen, said chemical species detach from said matrix such that said matrix becomes an essentially hydrophilic nature). Therefore claims 1 and 17-18 are obvious over Kumar in view of Keller and Baker et al.

Response to Arguments

Applicant's arguments filed May 8, 2009 have been fully considered but they moot in light of the new grounds of rejection.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635